United States Court of Appeals

for the Second Circuit

APPELLEE'S BRIEF

75-7122 Orginal

To be Argued by
David R. Spiegel

B
P/S

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs-Appellants,

-against- 75-7122

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; etc., et al.,

Defendants-Appellees.

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BRIEF

BRIEF ON BEHALF OF APPELLEES INGRAHAM AND THE PUBLIC HEALTH COUNCIL

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UNITED STATES COURT OF APPEALS
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DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs-Appellants,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; THE PUBLIC HEALTH COUNCIL of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education, and Welfare of the United States of America,

Defendants-Appellees.

75-7122

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BRIEF ON BEHALF OF APPELLEES INGRAHAM AND THE PUBLIC HEALTH COUNCIL

Facts and Prior Proceedings

A. Background

Plaintiffs are four, non-physician, self-employed clinical laboratory directors, operating laboratories in the City and State of New York. As such they perform a large variety of tests on patients with whom they do not have actual contact.

Pursuant to § 574, subd. 1 of the New York State Public Health Law and Article 13 of the New York City Health Code, plaintiffs are required to obtain a laboratory permit in order to maintain their operations. To retain the permit, plaintiffs are required to submit to periodic proficiency tests in whcih they must analyze chemical test samples given to them by the City and State (Public Health Law, § 576, subd. 2). The results are then graded by the appropriate governmental agencies (§ 576, subd. 3). If the grades consistently fall below certain minimum standards, the laboratory may lose its permit and thereby become subject to certain penalties (id. § 578).

The laboratories covered by the proficiency testing procedures are defined as:

> "all laboratories within the state, except laboratories operated by the state or the federal government or by a licensed physician, osteopath, dentist or pediatrist who performs laboratory tests, or procedures, personally or through his employees, solely as an adjunct to the treatment of his own patients".
>
> (id. § 579).

Authority for this provision is found, inter alia in 45 U.S.C. § 1395x, subds. 10, 11 and 20 C.F.R. § 405.1301(b). Authority for the proficiency testing procedure is found, inter alia, in 40 C.F.R. § 405.1304(a).

In this complaint, filed in the United States District Court for the Southern District of New York (Bonsal, J.) on April 23, 1973, plaintiffs alleged that the performance of the proficiency tests required them to use their own reagents at great expense to themselves (Compl. ¶¶ 12, 16) and that this was "a seizure of property in the form of labor and materials without compensation under color of state law and in violation of due process law and the Thirteenth Amendment to the United

States Constitution" (Compl. ¶ 19). Plaintiffs further alleged that they were denied equal protection of the law because the applicable federal statutes and regulations (42 U.S.C. § 1395x, subds. 10, 11; 20 C.F.R. § 405.1301[b]) and the state statute enacted pursuant thereto (Public Health Law § 579) had the effect of exempting from proficiency testing all laboratories operated by a licensed physician, osteopath, dentist or pediatrist who performs laboratory tests or procedures, personally or through his employees, solely as an adjunct to the treatment of his own patients. Plaintiffs, as directors of independent laboratories, did not qualify for this exemption.

The complaint sought monetary damages as well as injunctive relief against the state defendants, a) enjoining them from requiring plaintiffs to perform any more performance testing, and b) in the alternative, requiring them to apply the proficiency testing provisions to persons presently exempt under Public Health Law § 579. Plaintiffs also asserted that 42 U.S.C. § 1395x, subds. 10, 11 and 20 C.F.R. § 405.1301(b) were unconstitutional.

Subsequently, through motions raised by their respective attorneys, the various defendants herein moved to dismiss the complaint on the ground that it failed to set forth a substantial federal question.

B. Decision Below

After numerous adjournments in order to permit the various parties herein an opportunity to complete their respective pleadings, the District Court, in a decision filed on December 3, 1974, granted judgment on the pleadings for the defendants and dismissed the complaint.

With respect to the due process claim, the court commented that defendants' permit and proficiency procedures were an entirely valid exercise of their police power:

> "The defendants' permit and proficiency testing programs are essential to protect the public from the consequences of incompetent clinical laboratory testing. To achieve this goal, it is appropriate that the State and City require clinical laboratories to obtain permits based upon proficiency tests. Therefore, these programs are well within the bounds of the State's police power".
>
> (Record, A. 86).

The Court then went on to note:

> "Plaintiffs' claim that they are deprived of property without just compensation is also without merit. Reasonable regulations restricting the use of property in order to safeguard the the public's health do not constitute a compensable appropriation of property for public use....Plaintiffs therefore must bear the cost of complying with such regulations".
>
> (A. 87)

The court also dismissed plaintiffs' equal protection claim, noting pertinently:

> "The distinction drawn by the State clearly passes this test for rationality. As noted with respect to plaintiffs' due process claim, clinical laboratories have no contact with the patient aside from the specimen taken from his body. Therefore, there is [a] greater possibility that erroneous laboratory results will go undetected than when an attending physician, who knows the patient's symptoms and history, obtains an inaccurate test result".
>
> (A. 88)

Finally the court dismissed a belated contention by plaintiffs, advanced for the first time in their papers in opposition to the defendants' motion to dismiss (see, e.g., Affidavit of Rose Berman at A. 58-74) that the defendants --

in particular, the City defendants -- had been guilty of lax and discriminatory enforcement of their statutes and regulations. The Court observed:

> "Plaintiffs fail to allege in their complaint that defendants had knowledge of these violations...
>
> "If plaintiffs feel that defendants are failing to observe the standards prescribed in the statutes and regulations, they should seek relief from the administrative agencies involved and, if that fails, in the state courts".
>
> (A. 88-89).

An order was entered pursuant to the decision on December 23, 1974.

POINT I

THE COURT BELOW HAS PROPERLY CONCLUDED THAT PLAINTIFFS FAILED TO SET FORTH A SUBSTANTIAL FEDERAL QUESTION.

A closer reading of plaintiffs' appellate brief clearly indicates that there has been an astounding shift in the focus and emphasis of this action from the filing of the complaint to the present time. Plaintiffs now assert that they have no

quarrel with the concept of proficiency testing or the fact that they should be tested (Plts. Brief, p. 14); instead, they argue that it is the manner in which they are tested which underlines this action -- that they are invidiously discriminated against vis-a-vis private doctors, who, pursuant to federal and state statutes are exempt from proficiency testing, and vis-a-vis other persons who benefit from the sloppy administration of the pertinent statutes. However, despite this abrupt shift in tactics, it is clear that all of the issues herein are fully encompassed within the scope of the lower court holding and that Judge Bonsal quite properly concluded that plaintiffs' claims fail to raise a substantial federal question within the meaning of recent, pertinent Supreme Court decisions. See Hagans v. Lavine, 415 U.S. 528, 536-537 (1974); Goosby v. Osser, 409 U.S. 512 (1973).

A. The proficiency testing program is a valid exercise of the state's police power; as such any incidental taking of plaintiffs' property is immaterial and irrelevant

Plaintiffs' claims must be viewed against the historic background surrounding the legislative enactment of the proficiency testing program. This background underscores the reality noted by the opinion below (A. 86) that the program

is a prefectly valid and acceptable exercise of the State's police power in the field of medicine to regulate practices which violate legitimate aims of public policy. See Head v. New Mexico Board of Examiners in Optometry, 374 U.S. 424, 429 (1963); Williamson v. Lee Optical of Oklahoma, Inc., 348 U.S. 483 (1955); Parker v. Brown, 317 U.S. 341, 360 (1942).

As stated in the affidavits of William Kaufmann, M.D., the Director of the Clinical Laboratory Center in the Division of Laboratory and Research of the New York State Department of Health (A. 47-57) and Sylvia Blatt, Assistant Director, Bureau of Laboratories, Division of Improvement of the Department of Health of the City of New York (A. 26-37, SA1-6) the laboratory program in which plaintiffs are required to participate was a legislative response to shocking instances of laboratory incompetence having untold consequences to the health of every citizen of the State of New York.

Prior to the enactment of the Clinical Laboratory Provisions of the Public Health Law, the power of the State Commissioner of Health to regulate the operation and performance of clinical laboratories was limited to those laboratories which voluntarily sought his regulation. The result was that clinical

laboratory work was being performed at a dangerously low level as a result of inaccuracy in testing, inadequacy of instrumentation, lack of fundamental scientific knowledge, and outright fraudulence. This widespread and potential danger to the health of every citizen of New York State precipitated a message from the Governor to the 1964 Legislature in which he stated that clinical laboratories and their personnel were not subject to adequate supervision. There had been reports from the State Department of Health of shocking instances of incompetence on the part of some clinical laboratories. The Governor recommended legislation to provide new public health protection by establishing a system for the supervision and regulation of clinical laboratories and blood banks. McKinney's 1964 Session Laws of New York, pp. 1938-1939. The legislative response was the enactment of Title V, §§ 570-581 of the Public Health Law. These are the statutes which plaintiffs attack in the instant case.

In passing the provisions of Title V, the Legislature said:

> "It is the purpose of this article to promote the public health, safety and welfare by requiring the licensure of clinical laboratories and blood banks, by establishing minimum qualifications for laboratory directors,

> and by requiring that the performance of all procedures employed by clinical laboratories and blood banks shall meet minimum standards accepted and approved by the department". (Public Health Law, § 570).

Applying these principles to the instant case, it is clear that these clinical laboratory provisions easily pass constitutional muster. The potential danger to the health and well-being of every citizen of the State of New York can hardly be emphasized enough, since clinical laboratories perform tests and analyses the results of which are relied upon by physicians for use in diagnosis and treatment of disease and on which the patient's life hangs. It needs little imagination to conjure up the potential consequences of inaccurate laboratory tests -- they can lead to unnecessary treatment, medication, or surgery and/or undetected disease possibly resulting in death. As such, the regulation of clinical laboratories, to say the least, is a proper exercise of the police power of the state.

Plaintiffs' allegation that they receive no compensation for expenses incurred in the course of complying with these clinical laboratory testing provisions raises no substantial federal question. It is well recognized that the enforcement of uncompensated obedience to a statute passed in the legitimate

exercise of the police power is not a taking of property without due process of law. New Orleans Public Service v. New Orleans, 281 U.S. 682, 687 (1929); Chicago & Alton R.R. v. Tranbarger, 238 U.S. 67, 78 (1914). And, no doubt, given the right to regulate (see supra), it is well settled law that the cost of regulation may be placed upon the clinical laboratories. North Dakota State Board of Pharmacy v. Snyder's Drug Stores, Inc. 414 U.S. 156 (1973); Charlotte C & AR Co. v. Gibbes, 142 U.S. 386 (1892); Pent R. Books, Inc. v. United States Postal Service, 328 F. Supp. 297, 310 (E.D.N.Y. 1971). See also, analogously 15 U.S.C. § 780(b)(8) (concerning the Securities and Exchange Commission); 12 U.S.C. § 482 (concerning the expenses of examining national banks); 7 U.S.C. § 2153 (the Animal Welfare Act). See too People v. Automobile Transporters Welfare Fund, 17 A D 2d 446 (1962) affd. 13 N Y 2d 814, cert. den. 376 U.S. 908 (expenses of examination).

B. Plaintiffs' Equal Protection Claims are without merit

With respect to plaintiffs' equal protection claim involving the classification in § 579 of the Public Health Law, it is clear that since this involves neither a fundamental constitutional right (e.g., Dunn v. Blumstein, 405 U.S. 330, 338-42 [1972]) nor a suspect classification (Harper v. Virginia Board of Elections, 383 U.S. 663, 669 [1969]), no "searching judicial scrutiny" of the challenged provision is required.

San Antonio Independent School District, et al. v. Rodriguez, 411 U.S. 1, 40 (1973). Rather, the basic inquiry here is "whether the challenged distinction rationally furthers some legitimate, articulated state purpose", McGinnis v. Royster, 410 U.S. 263, 276 (1973). This, as the lower court has already indicated, it most certainly does (A. 87-88).

As stated in the affidavit of William Kaufmann (A. 54-56), in order to conduct a meaningful proficiency testing program and to determine a permit laboratory's capability to perform, one must not only determine the capability of the persons who perform the numerous and varied laboratory tests but also the adequacy of equipment, materials, reagents and instruments used by the laboratory. On this performance depends the physician's diagnosis and frequently hangs the patient's life. This type of laboratory operation is a far cry from the situation where a physician, osteopath, dentist or pediatrist operates a laboratory solely in conjunction with the treatment of his own patients. While this exempt group may be unqualified to operate a clinical laboratory whose permit authorizes it to do one or more categories of procedures, each of which categories may include a great number of laboratory tests of varying degrees of difficulty, it is certainly qualified to conduct the relatively few routine tests performed by physicians in their own

office laboratories. The particular tests performed by physicians or their employees are related to a great extent to the medical specialty which the physician practices. The legislature could reasonably conclude that the qualifications which one must possess to practice medicine or a specialty of of medicine, see Education Law §§ 6501, 6502, are different from those necessary to insure the proper direction of a clinical laboratory. Secondly, the legislature could also reasonably conclude that the qualifications which one must possess to practice medicine or one of its specialties would include the ability to perform laboratory tests relating to the practice of that specialty. See Derman v. Ingraham, 47 Misc 2d 346 (Sup. Ct. Ulster Co., 1965) affd. 25 A D 2d 795 (3d Dept. 1966), leave to appeal denied, 18 N Y 2d 579 (1966). See also United States v. Carolene Products Co., 304 U.S. 144, 151 (1938).

It should also be noted that a private physician has a far greater stake than any independent laboratory in obtaining accurate test results. Faulty laboratory work by the physician's own laboratory may mean an incorrect diagnosis, inappropriate treatment, damage to patients, and a malpractice suit or professional disciplinary proceeding against the physician. The permit laboratory, on the other hand, does work for many physicians who are not in a position to evaluate the

the laboratory's performance and must rely on the State or City to assure that the laboratory's performance is accurate. As such, the statutory exemption is, to say the least, rational and constitutionally valid. See case citations, supra, pp. 12-13.

Plaintiffs equal protection claims with respect to Section 579 have already been rejected in an analogous lawsuit in the state courts, brought by licensed physicians (pathologists) who were directors of clinical laboratories and were subject to regulations similar to those at issue herein. See Derman v. Ingraham, cited supra, p. 14. There the court held pertinently:

> "The distinction between physicians who operate laboratories for the diagnostic benefit of other physicians instead of their own patients, and physicians who perform laboratory tests solely as an adjunct to the treatment of their own patients, is a classification which has a reasonable and rational basis and hence is within the power of the legislature to make....such a classification is not obnoxious to the equal protection of the laws since it is not clearly and actually arbitrary...the legislature could reasonably conclude the qualifications which one must process to practice medicine, including the specialty of pathology....are somewhat different then those necessary to insure the proper direction of a clinical laboratory".
>
> (47 Misc 2d at 349).

Plaintiffs also assert that they are victimized by poor preparation of test samples and by a failure to require certain private physicians who operate general laboratories to comply with the same licensing and testing requirements that they are obliged to comply with (Aplt's. Br. pp. 16-17). The short answer to these claims is that they are directed against the City defendants rather than the State defendants (See Affidavit of Rose L. Berman at A. 58-74). However, in any event, plaintiffs have failed to show actual knowledge by the defendants with regard to the alleged abuses. Thus, as the lower court has aptly noted, the claims must be dismissed for failure to show purposeful discrimination (A. 89). Moreover, if there is any basis to plaintiffs' claims, they should, as the lower court has directed, advise the appropriate administrative agencies. However, if mispractices do exist their correction would have no bearing on plaintiffs' own procedures; the idea would be to correct undetected abuses, rather than to create more abuses.

CONCLUSION

THE DECISION OF THE LOWER COURT
SHOULD IN ALL RESPECTS BE AFFIRMED

Dated: New York, New York
April 10, 1975

Respectfully submitted,

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Attorney for Defendants
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STATE OF NEW YORK)
: SS.:
COUNTY OF NEW YORK)

SUSAN D. CHIECO , being duly sworn, deposes and says that she is employed in the office of the Attorney General of the State of New York, attorney for State Appellees herein. On the 17th day of April , 1975 , she served the annexed upon the following named persons:

ROTHBLATT, ROTHBLATT, SEIJAS & PESKIN Attorneys for Appellants 232 West End Avenue New York, New York 10023	W. BERNARD RICHLAND, ESQ. c/o Corp. Counsel of the City of New York Attorneys for City Defs. Municipal Bldg. New York, N.Y. 10007	HON. P. CURRAN U.S. Attny. Attny. for Fed'l Defs. U.S. Courthouse Foley Square N.Y. N.Y. 10007

Attorneys in the within entitled action by depositing a true and correct copy thereof, properly enclosed in a post-paid wrapper, in a post-office box regularly maintained by the Government of the United States at Two World Trade Center, New York, New York 10047, directed to said Attorneys at the address es within the State designated by them for that purpose.

Susan D. Chieco

Sworn to before me this
17th day of April , 1975

Assistant Attorney General
of the State of New York